

### **Remarks**

Claims 1-17 and 20-36 are pending upon entry of the foregoing amendments. Claims 4, 8-11, and 29-30 have been withdrawn as being directed to a non-elected species.

### **Amendments to the Specification and Drawings**

The description (specification) and drawings have been amended to literally incorporate material that previously was incorporated only by reference to a published U.S. Patent Application. Specifically, the new drawings and description thereof is taken from U.S. Patent Application No. 10/641,507, published as U.S. Patent Publication No. 2004/0121486. This is incorporated by reference, for example, at page 9, lines 17-20; page 13, lines 21-24; and page 17, lines 14-16, of the present application. No new matter has been added.

### **Amendments to the Claims**

Claim 1 has been amended to specify that the device further includes a plurality of discrete reservoir caps separating the release system from an environment outside of the reservoirs and that the device further includes means for disintegrating one or more of the reservoir caps to expose the release system to the environment, *wherein the disintegration occurs by electrothermal ablation*. Support for this amendment is found in original claims 18-19 and in the specification at page 14, lines 12-29. Claims 18-19 have accordingly been cancelled.

Claims 1-3, 5-7, 12-16, 23, and 31-35 have been amended to (i) clarify that the neural electrical stimulator comprises at least one stimulation electrode (ii) clarify the positive limitations and functional relationships of elements, (iii) more clearly define the method steps, (iv) correct grammatical or typographical errors, and (v) correct the antecedent basis of claims.

New claim 36 has been added. Support for this amendment is found in the specification at least at page 24, lines 6-17; FIGS. 5-6 and the description thereof.

### **Information Disclosure Statements**

The Office Action indicated that a copy of the reference Santini, et al., "Microchips as Controlled Drug-Delivery Devices," *Angew Chem. Int. Ed. Engl.* 33(14): 2396-407 (2000) was not submitted with the Information Disclosure Statement mailed February 25, 2004, and therefore was not considered. The Examiner's premise is incorrect; Applicants did in fact submit a copy of that reference. In fact, as indicated by the stamped, returned postcard from the Office, the Office did receive on March 1, 2004, all eleven of the reference copies submitted with that IDS. Nevertheless, a replacement copy of the reference is herewith resubmitted.

A supplemental information disclosure statement and the appropriate fee therefor are also submitted herewith.

### **Species Election Requirement**

The Office Action indicates the claims are directed to the following patentably distinct species and subspecies and requires election to a single species:

Species I – Figure 2

Subspecies A: embodiment of claim 4

Subspecies B: embodiment of claim 5-6

Species II – Figures 3 and 4

Applicants confirm the provisional election, with traverse, of Species I and Subspecies **B**. It is noted that the Office Action (¶ 2) is incorrect insofar as it indicates that a provisional election

was made to Embodiment A. Claims 1-3, 5-7, 12-17, 20-28, and 31-36 read on the elected species and subspecies.

Applicants traverse on the grounds that search and consideration of both of the species would not present an undue burden. In fact, M.P.E.P. 806.04(a) and 37 C.F.R. § 1.141 provide that a reasonable number of species may be claimed in one application. Two is smallest possible plurality. Furthermore, contrary to the requirements of M.P.E.P. 814, the Office Action fails to point out “the particular limitations in the claims and the reasons why such limitations are considered to restrict the claims to a particular disclosed species” as needed to make clear the requirement espoused in the Office Action. The basis of the species election requirement is unclear from the mere listing of figures as “species.”

#### **Claim Objections**

Claim 6 was objected to as incorrectly reciting dependency from claim 4, rather than from claim 5. The objection is traversed. Claim 6 has been amended to correctly recite that it depends from claim 5.

#### **Rejections Under 35 U.S.C. § 112**

Claims 1-3, 5-7, 12-17, 20-28, and 31-35 were rejected under 35 U.S. C. § 112, second paragraph, as indefinite. The rejection is respectfully traversed if applied to the claims as amended.

M.P.E.P. § 2173.02 states that the essential inquiry pertaining the requirement for definiteness under 35 U.S.C. § 112 is “whether the claims set out and circumscribe a particular subject matter with a *reasonable degree of clarity and particularity*” and that “definiteness of claim language must be analyzed, not in a vacuum, but in light of ... the claim interpretation that

would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” M.P.E.P. § 2173.02 also states that some “latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.” In the present case, the claims as amended are clear and definite, such that the metes and bounds of the claims are defined with a reasonable degree of particularity and distinctness to satisfy the requirements of 35 U.S.C. § 112, second paragraph.

#### **Rejections under 35 U.S.C. § 102**

Claims 1-3, 5-7, 12-17, 20-28, 31-32, and 35 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent Application Publication No. 2002/0111601 to Thompson (hereinafter “Thompson”). The rejection is respectfully traversed if applied to the claims as amended.

#### **The Claimed Devices and Methods**

Applicants’ claimed devices include reservoirs that are closed off from an external environment by reservoir caps that can be controllably disintegrated to release or expose the contents of (e.g., drug in) the reservoirs. The claimed devices include a *particular* means for disintegrating the reservoir caps, means that utilize a special technique: electrothermal ablation. In electrothermal ablation, the reservoir cap is disintegrated in a manner analogous to the failure of a conventional electrical fuse. That is, sufficient electrical current is passed directly through the reservoir cap to cause it to heat and rupture.

#### **Thompson**

Thompson discloses an implantable medical device that includes a catheter having a port and a cap member which is oxidized and dissolved into the surrounding fluids to allow the drug to be released from the catheter. Disintegration depends on creation of an electrochemical cell

with fluids in vivo. That is, Thompson discloses an *electrochemical* mechanism for disintegrating a cap member. The structures and methods of Thompson therefore are entirely distinct from those for electrothermal ablation. Thompson clearly fails to disclose or remotely suggest a structure or means for electrothermal ablation and therefore clearly fails to teach Applicants' claimed devices and methods.

**Rejections under 35 U.S.C. § 103(a)**

Claim 17 was rejected under 35 U.S.C. § 103(a) as obvious over Thompson in view of U.S. Patent 5,797,898 to Santini, Jr. et al. (hereinafter "Santini"). Claim 33 was rejected under 35 U.S.C. § 103(a) as obvious over Thompson in view of U.S. Patent Application Publication No. 2002/0055761 to Mann et al. (hereinafter "Mann"). Claim 34 was rejected under 35 U.S.C. § 103(a) as obvious over Thompson in view of U.S. Patent 6,587,719 to Barrett et al. (hereinafter "Barrett"). The rejections are respectfully traversed if applied to the claims as amended.

As discussed above, Thompson does not disclose or suggest a device that includes means for *electrothermal ablation* of a reservoir cap to control opening of a reservoir. Nothing in Santini, Mann, or Barrett, alone or in combination, can be construed to supplement this deficiency. Applicants' claimed devices and methods are clearly not taught or suggested by any combination of Thompson or these secondary references.

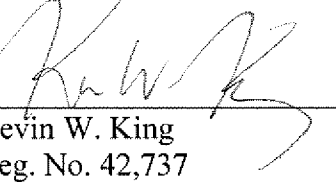
**Conclusions**

The claims as amended are clear, definite, novel and non-obvious over the prior art of record. Prompt allowance of each of pending claims 1-17 and 20-36 is therefore respectfully solicited.

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AMENDMENT AND  
RESPONSE TO OFFICE ACTION

The undersigned kindly invites the Examiner to contact him by telephone (404.853.8068) if any outstanding issues can be resolved by conference or examiner's amendment.

Respectfully submitted,



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